510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: **K073665**

A. Submitter

Natus Medical Inc.
1501 Industrial Road
San Carlos, CA 94070

JAN 25

Contact

Tom Boles
(650) 801-7262

Date Summary Prepared

January 15, 2008

B. Device Names

Classification Name	Stimulator, Auditory Evoked Response
Common/Usual Name	Hearing Screener
Proprietary Name	ALGO® 5 Newborn Hearing Screener

C. Predicate Device:

ALGO® 3 Newborn Hearing Screener (K013137)

D. Device Description

The ALGO 5 detects the auditory brainstem response (ABR) to a series of stimulus clicks ('clicks'), which screens the entire hearing pathway from the outer ear to the brainstem. The ABR is not affected by the status of the middle ear, and evaluation of middle ear status is not required prior to ABR detection. The ALGO 5 generates soft clicks at 35 dB nHL or at 40 dB nHL ('normal hearing level' scale) which are delivered to the infant's ears through an Acoustic Transducer Assembly cable (ATA) to disposable earphones (Flexicouplers™ Disposable Earphones).

Each click evokes a series of identifiable brain waves from the auditory brainstem area of the infant's brain. Sensors (Jelly Tab™ Sensors) applied to the infant's skin pick up the brain wave response and transmit the signals to the screener via the Patient Cable Attachment (PCA) and Preamplifier (Preamp) assemblies. The ALGO 5 uses advanced signal processing technology to separate the ABR from background noise and from other brain activity.

The ALGO 5 uses a statistical algorithm to determine if there is a response to the stimulus, and if a response is detected, whether the response is consistent with a template of ABRs derived from normal hearing infants (automated auditory brainstem response technology, AABR).

E. Intended Use

The ALGO 5 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR® technology. The screener is intended for babies between the ages of 34 weeks (gestation age) and 6 months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening.
The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good heath and about to be discharged from the hospital. A typical screening process can be

completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

Contraindications for Use:

Screening infants with known neurologic conditions should be done only under well-informed medical and/or audiological supervision.

F. Comparison with Predicate Device

The ALGO 5 is a hardware and software modification of the ALGO 3 Newborn Hearing Screener. The ALGO 5 and the ALGO 3 have the same intended use and use the same operating principle.

Based on the data and information presented here, the ALGO 5 Newborn Hearing Screener is substantially equivalent to the ALGO 3 Newborn Hearing Screener currently manufactured and distributed by Natus Medical, Inc.

G. Non-clinical Performance Data

Summaries of design verification and validation are included to demonstrate that the ALGO 5 performs equivalently to the ALGO 3.

H. Clinical Performance Data

No clinical performance data are included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Natus Medical, Incorporated
% Mr. Tom Boles
QA Manager
1501 Industrial Road
San Carlos, California 94070

Re: K073665
Trade/Device Name: ALGO 5 Newborn Hearing Screener
Regulation Number: 21 CFR 882. 1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: December 20, 2007
Received: December 26, 2007

Dear Mr. Boles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K073665**

Device Name: ALGO 5 Newborn Hearing Screener

Indications for Use:

The ALGO 5 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR® technology. The screener is intended for babies between the ages of 34 weeks (gestation age) and 6 months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening.

The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good heath and about to be discharged from the hospital. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

Prescription Use __X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073665